

## DETAILED ACTION

### Status of Action

Receipt of Amendments/Remarks filed on 04/06/2011 is acknowledged.

Receipt of certified copy of the English translation of French Application No. 03/00507 on 04/06/2011 is acknowledged. It has been considered and placed in the file.

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Kenneth Meyers on 05/06/2011.

- **Claim 1 at line 3 and claim 8 at line 2:** please amend **3**-methoxy-PREG to **3 $\beta$** -methoxy-PREG.
- **Claim 1 at line 2:** please deletes the comma "," between the words patient and comprising.
- **Claim 3 is cancelled.**
- **Amendment to the originally filed specification (filed on 07/15/2005):**
  - Please amends **3**-methoxy-PREG to **3 $\beta$** -methoxy-PREG at:

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Page 4: line 3, 4, 14, 23, 27, 28;

Page 5: line 21;

Page 6: line 32;

Page 7: line 14, 32;

Page 8: line 1, 11;

Page 10, line 23;

Page 11: line 8, 12, 15, 19, 21, 30;

Page 12: line 2, 3, 6, 12, 22, 29;

Page 13: line 4, 8, 12, 18, 28;

Page 14: line 6, 10, 11, 23;

Page 15: line 6, 10, 32;

Page 16: line 1, 16;

Page 17: line 29;

Page 20: line 7, 10;

Page 21: line 19.

- **For Amendment to the Specification (filed on 04/06/2011):**
  - Please amends **3**-methoxy-PREG to **3β**-methoxy-PREG as indicated at:  
Page 5: line 10, 18 of the amendment;  
Page 6: line 2, 6, 15, 20, 21 of the amendment.

### **Reasons for Allowance**

Accordingly, claims 1-2, 4-5 and 8 of the instant application are allowed.

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The following is an examiner's statement of reasons for allowance:

The amended claims 1-2, 4-5 and 8 are drawn to a method of treating an acute or chronic spinal cord lesion in a patient by administering to the patient a composition comprising 3 $\beta$ -methoxy-pregna-5-ene-20-one (3 $\beta$ -methoxy-PREG), wherein the composition is administered to the patient in an amount (50-2500 mg) effective to treat the acute or chronic spinal cord lesion, and wherein the acute or chronic spinal cord lesion is spinal cord compression.

The instant invention is unobvious over the reference WO 03/039554 document (equivalent to EP 1310258 document) by Baulieu et al. because the instant invention is directed to a method of treating spinal cord lesion, whereas the method of Baulieu is directed to a method for enhancing memory and cognitive function in mammals resulting from a cause, i.e. age, neurological disorders, neuropsychiatric disorders, neurodegenerative disorders or injury. Therefore, the invention as a whole would not have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

In addition, the instant claims have overcome the previous rejection under 35 U.S.C. § 112 first paragraph (scope of enablement) by amending the specification and claims by replacing "medullary compression" with "spinal cord compression". Applicants explained that these amendments are necessary to adapt the English translation of the application to the French priority application because translation of the French expression "*compression medullaire*" into "medullary compression" should have been "spinal cord compression". Applicants also explained that Example 5 (see: specification,

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page 18, lines 22-29 for Example 5 and page 14, lines 26-32 for Figure 7) disclosed the term “medullary compression” which should have been “spinal cord compression” because the results of experiments using an animal model of trauma in the example 5 was described using BBB score. Applicants explained that the BBB score is widely used in the relevant art to evaluate the efficiency of spinal cord injury treatment, as evident by the submitted literatures (see: literatures attached as a part of Amendment to the Specification and Remarks filed on 04/06/2011). Applicants’ explanations are persuasive and the correct English translation of the French expression “*compression medullaire*” into “spinal cord compression” has been verified and confirmed by the USPTO in-house STIC French translator (Steven Spar). The support for treating spinal cord compression by administering 3 $\beta$ -methoxy-pregna-5-ene-20-one (3 $\beta$ -methoxy-PREG or compound 43B) is provided in the Example 5 and Figure 7 of the instant specification, which showed that animals treated with compound 43B resulted in significantly higher BBB score compared to the control animals as of post-operation day 7.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance.

### **Contact Information**

Any inquiry concerning this communication from the Examiner should direct to Helen Mei-Ping Chui whose telephone number is 571-272-9078. The examiner can

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normally be reached on Monday-Thursday (7:30 am–5:00 pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where the application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either PRIVATE PAIR or PUBLIC PAIR. Status information for unpublished applications is available through PRIVATE PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the PRIVATE PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/H. C./  
Examiner, Art Unit 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616